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**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF CALIFORNIA**

PAULA AMARAL,	)	CIVIL ACTION NO.:
	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	
COOK INCORPORATED; COOK	)	<b>COMPLAINT AND DEMAND FOR JURY</b>
MEDICAL LLC f/k/a COOK MEDICAL	)	<b>TRIAL</b>
INCORPORATED; and COOK GROUP	)	
INCORPORATED,	)	
Defendants,	)	
	)	
	)	

Plaintiff PAULA AMARAL (hereinafter "Plaintiff"), by and through her attorneys, hereby files this, Complaint and Demand for Jury Trial, against Defendants COOK INCORPORATED, COOK MEDICAL LLC f/k/a COOK MEDICAL INCORPORATED; and COOK GROUP INCORPORATED (hereinafter "Cook Defendants"), and alleges the following:

/ / /

**I. Jurisdiction**

1. The Court has subject matter jurisdiction over this matter because the parties are citizens of different states and the amount in controversy exceeds \$75,000.

2. The Court has personal jurisdiction over the Cook Defendants because they have sufficient minimum contacts such that asserting jurisdiction over the defendants does not offend traditional notions of fair play and substantial justice. *International Shoe v. Washington*, 326 U.S. 310, 325 (1945).

**II. General Background**

3. This is an action for damages relating to Defendants' development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling defective product sold under the name "inferior vena cava filter" (hereinafter "IVC Filter").

4. Cook IVC Filters are associated with, and cause, an increased risk for serious injury and death as a result of adverse events including: tilting, perforation, fracture, breakage and migration.

5. At all times relevant to this action, Cook intentionally, recklessly, and/or negligently failed to act as to the known failures and injuries associated with its devices and/or failed to warn about and concealed, suppressed, omitted, and/or misrepresented the risks, dangers, defects and disadvantages of its IVC Filters.

6. At all times relevant to this action, Cook intentionally, recklessly, and/or negligently advertised, labeled, promoted, marketed, sold and/or distributed its IVC Filters as a safe medical device when in fact Cook had reason to know, and/or did know, that its IVC Filters were not safe for its intended purposes, and that its IVC Filters caused serious injury and death.

7. At all times relevant to this action, Cook is and was strictly liable for injuries caused by its IVC Filters because the devices are unreasonably dangerous and not accompanied by adequate warnings about its danger.

**III. Parties**

8. Plaintiff, Paula Amaral, at all times relevant to this action is and was a citizen of and resident of Fresno County in the state of California.

9. Defendant Cook Incorporated is an Indiana Corporation with its principal place of

1 business located at 750 Daniels Way, P.O. Box 489, Bloomington, Indiana. On information and  
2 belief, Cook Incorporated is a privately-owned corporation with wholly owned subsidiaries that it  
3 controlled, including Cook Medical, LLC f/k/a Cook Medical Incorporated, and Cook Group  
4 Incorporated.

5 10. Defendant Cook Medical, LLC is a privately-owned Indiana limited liability company  
6 with its principal place of business located at 1025 West Acuff Road, Bloomington, Indiana 47404.  
7 Cook Medical, LLC was formerly known as Cook Medical Incorporated.

8 11. Defendant Cook Group Incorporated is an Indiana Corporation with its principal place  
9 of business located at 750 Daniels Way, P.O. Box 489, Bloomington, Indiana.

10 12. Defendants Cook Incorporated, Cook Medical LLC f/k/a Cook Medical Incorporated,  
11 and Cook Group Incorporated are hereinafter collectively referred to as “Cook Defendants” or  
12 “Cook.”

13 13. At all relevant times, the Cook Defendants were in the business of designing, setting  
14 specifications for, manufacturing, preparing, compounding, assembling, processing, marketing,  
15 packaging, and selling Gunther Tulips inferior vena cava filters to distributors and sellers, including  
16 hospitals, for implantation by physicians at hospitals in patients throughout the United States,  
17 including in California.

18 14. At all relevant times, each of the Cook Defendants regularly marketed, distributed and  
19 sold Gunther Tulip filters throughout California and sold the Gunther Tulip filter in California for  
20 resale and implantation into human patients, including Plaintiff.

21 15. At all relevant times, each of the Cook Defendants and their directors and officers acted  
22 within the scope of their authority. At all relevant times each Cook defendant was responsible for  
23 each other’s actions and inactions; and each Cook defendant acted on behalf of each other Cook  
24 Defendant.

25 16. At all relevant times, the Cook Defendants possessed a unity of interest between  
26 themselves and Cook. Cook exercised control over its subsidiaries and affiliates. As such, each Cook  
27 Defendant is responsible jointly and severally to Plaintiff for her injuries, losses and damages.

28 17. Venue is proper in this district because a substantial part of the events or omissions

giving rise to Plaintiff's claims occurred in this district. See 28 U.S.C. § 1391(b)(2).

#### IV. Factual Background

##### A. Cook Inferior Vena Cava Filters Generally

18. Defendants design, research, develop, manufacturer, test, market, advertise, promote, distribute, and sell products that are sold to and marketed to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. Defendants' products include, the Cook Select Vena Cava Filter and the Gunther Tulip Filter (collectively referred to herein as "Cook Filters"), which are introduced via a coaxial introducer sheath system.

19. Defendants sought Food and Drug Administration ("FDA") approval to market the Cook Filters and/or its components under Section 510(k) of the Medical Device Amendment.

20. Section 510(k) allows marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of the said device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" process in an amicus brief filed with the Third Circuit in *Horn v. Thoratec Corp.*, 376 F.3d 163, 167 (3d Cir. 2004):

A manufacturer can obtain an FDA finding of "substantial equivalence" by submitting a premarket notification to the agency in accordance with section 510(k)...A device found to be 'substantially equivalent' to a predicate device is said to be "cleared" by FDA (as opposed to "approved" by the agency under a [premarket approval]). A pre-market notification submitted under 510(k) is thus entirely different from a [pre-market approval] which must include data sufficient to demonstrate that the device is safe and effective. (Emphasis in original).

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470,478-79 (1996), the Supreme Court similarly described the 510(k) process, observing:

If the FDA concludes on the basis of the [manufacturer's] §510(k) notification that the device is 'substantially equivalent' to a pre-existing device, it can be marketed without further regulatory analysis...The §510(k) notification process is by no means comparable to the [premarket approval] process; in contrast to the 1,200 hours necessary to complete a PMA review, the §510(k) review is completed in average of 20 hours...Section §510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets process quickly.

1 An IVC filter, like the Cook Filters, is a device designed to filter blood clots (called “thrombi”) that  
2 travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be  
3 implanted, either temporarily or permanently, within the vena cava.

4 21. The inferior vena cava is a vein that returns blood to the heart from the lower portion of  
5 the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and  
6 pelvis, through the vena cava into the lungs. Often these thrombi develop in the deep leg veins. The  
7 thrombi are called “deep vein thrombosis” or DVT. Once the thrombi reach the lungs they are  
8 considered “pulmonary emboli” or PE. An IVC filter, like the Cook IVC Filters, is designed to  
9 prevent thromboembolic events.

10 22. The Cook Filters are retrievable filters.

11 23. The Cook Celest® Vena Cava Filter has four (4) anchoring struts for fixation and eight  
12 (8) independent secondary struts to improve self-centering and clot trapping.

13 24. The Gunther Tulip® Vena Cava Filter has a top hook and (4) anchoring struts for  
14 fixation and on each strut, it has a “flower” formation that is shorter than the strut where a wire piece  
15 branches out on each side of the strut forming an overall “flower” type formation on each strut.

16 25. At all times relevant hereto, the Cook Filters were widely advertised and promoted by  
17 the Defendants as safe and effective treatment for prevention of recurrent pulmonary embolism via  
18 placement in the vena cava. At all times relevant hereto, Defendants knew its Cook Filters were  
19 defective and knew that defect was attributable to the design’s failure to withstand the normal  
20 anatomical and physiological loading cycles exerted in vivo.

21 26. A retrospective review of all Cook Gunther Tulip Filters and Cook Celest filters  
22 retrieved between July 2006 and February 2008 was performed. One hundred and thirty (130) filter  
23 retrievals were attempted but in 33 cases, the standard retrieval technique failed. The authors  
24 concluded that “unsuccessful retrieval was due to significant endothelialization and caval  
25 penetration” and that “hook endothelialization is the main factor resulting in failed retrieval and  
26 continues to be a limitation with these filters.” O. Doody, et al.; “Assessment of Snared-Loop  
27 Technique When Standard Retrieval of Inferior Vena Cava Filters Fail” Cardiovasc  
28 Intervent Radiol (Sept 4, 2008 Technical Note).

1           27. A retrospective review of 115 patients who underwent Cook Celect IVC filter insertion  
2 between December 2005 and October 2007 was performed. While filter insertion was successful in  
3 all patients, the authors also concluded that “[f]ailed retrieval secondary to hook endothelialization  
4 continues to be an issue with this filter.” O. Doody, et al; Journal of Medical Imaging and Radiation  
5 Oncology “Initial Experience in 115 patients with the retrievable Cook Celect vena cava filter” 53  
6 (2009) 64-68 (original article).

7           28. In a review of clinical data related to 73 patients who had Celect IVC filter implanted  
8 between August 2007 and June 2008, the authors found that the Celect IVC filter was related to a  
9 high incidence of caval filter leg penetration. Immediately after fluoroscopy-guided filter  
10 deployment in 61 patients, four filters (6.5%) showed significant tilt. Follow-up abdominal CT in 18  
11 patients demonstrated filter related problems in 7 (39%), which included penetration of filter legs in  
12 4 and fracture/migration of filter components in 1.

13           29. In a study of Gunther Tulip and Celect IVC filters implanted between July 2007 and  
14 May of 2009 reported by Cardiovascular Interventional Radiology electronically on March 30, 2011  
15 and published by journal in April 2012, one hundred percent of the Cook Celect filters and Gunther  
16 Tulip filters imaged after 71 days of implant caused some degree of filter perforation of the venal  
17 caval wall. Durack JC, et al, Cardiovasc Intervent Radiol., “Perforation of the IVC: rule rather than  
18 the exception after longer indwelling times for the Gunther Tulip and Celect Retrievable Filters,”  
19 2012 Apr.; 35(2):299-308. Epub 2011 Mar 30. The authors concluded: "Although infrequently  
20 reported in the clinical literature, clinical sequelae from IVC filter components breaching the vena  
21 cava can be significant." Defendants knew or should have known that their IVC filters were more  
22 likely than not to perforate the vena cava wall.

23           30. This same study reported that tilt was seen in 20 out of 50 (40%) of the implanted  
24 Gunther Tulip and Celect IVC filters and all tilted filters also demonstrated vena caval perforation.  
25 Defendants knew or should have known that their IVC filters were more likely than not tilt and to  
26 perforate.

27           31. While not inclusive of all medical studies published during the relevant time period, the  
28 above references show that the Defendants failed to disclose to physicians, patients and/or Plaintiff

1 that its Cook Filters were subject to breakage, tilt, inability of removal, and migration even though  
2 they knew or should have known the same was true.

3 32. At all times relevant hereto, the Defendants continued to promote the Cook Filter as safe  
4 and effective even when inadequate clinical trials had been performed to support long or short to  
5 safety and/or efficacy.

6 33. The Defendants concealed the known risks and failed to warn of known or scientifically  
7 knowable dangers and risks associated with the Cook Filters, as aforesaid.

8 34. The Cook Filters are constructed of conichrome.

9 35. The Defendants specifically advertise the conichrome construction of the filter as a  
10 frame which “reduces the risk of fracture.”

11 36. The failure of the Cook Filters is attributable, in part, to the fact that the Cook Filters  
12 suffer from a design defect causing it to be unable to withstand the normal anatomical and  
13 physiological loading cycles exerted *in vivo*.

14 37. At all times relevant hereto, the Defendants failed to provide sufficient warnings and  
15 instructions that would have put Plaintiff and the general public on notice of the dangers and adverse  
16 effects caused by implantation of the Cook Filters, including, but not limited to the design’s failure  
17 to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

18 38. The Cook Filters were designed, manufactured, distributed, sold and/or supplied by the  
19 Defendants, and were marketed while defective due to the inadequate warnings, instructions,  
20 labeling, and/or inadequate testing in light of Defendants’ knowledge of the products’ failure and  
21 serious adverse events.

22 39. That at all times relevant hereto, the officers and/or directors of the Defendants named  
23 herein participated in, authorized and/or directed the production and promotion of the  
24 aforementioned products when they knew or should have known of the hazardous and dangerous  
25 propensities of the said products, and thereby actively participated in the tortious conduct that  
26 resulted in the injuries suffered by the Plaintiff.

27 40. Plaintiff’s Cook Gunther Tulip Filter and Injuries  
28

1 41. On or about October 20, 2005, Plaintiff Paula Amaral was implanted with a Cook  
2 Gunther Tulip Vena Cava Filter.

3 42. The product identification sticker for the Cook Filter was included in her medical  
4 records and identified the device's lot number as 1515016.

5 43. On or about March 6, 2018, Plaintiff underwent a computed tomography ("CT") scan of  
6 her abdomen and pelvis. The CT scan revealed that the Cook Filter struts had moved since the filter  
7 was placed, with several of the struts extending outside Ms. Amaral's inferior vena cava into both  
8 her retroperitoneum and vertebra.

9 44. On or about July 9, 2019, Plaintiff underwent a complex inferior vena cava filter  
10 retrieval where her Cook Filter was noted as being "embedded, fractured and penetrating."  
11 Plaintiff's surgeon was able to remove the body of the filter and one fractured filter strut. However,  
12 Plaintiff's surgeon was unable to remove several fractured fragments of Plaintiff's Cook IVC Filter.

13 45. Despite undergoing this complex surgery to remove the device, several fractured filter  
14 struts remain retained in Plaintiff's body.

15 46. For the rest of her life, Plaintiff will require ongoing medical care and monitoring.

16 47. Plaintiff has also suffered significant, disfiguring injuries, including significant pain and  
17 distress restricting her ability to engage in activities of daily living.

18 48. Furthermore, Plaintiff has incurred substantial medical expenses as a result of Cook's  
19 defective device, and, on information and belief, she will continue to incur substantial medical  
20 expenses in the future.

21 **V. Count I: Strict Products Liability – Failure to Warn**

22 49. Plaintiff repeats and realleges all previous paragraphs.

23 50. Cook Filters were defective and unreasonably dangerous when they left the possession  
24 of the Defendants in that they contained warnings insufficient to alert consumers, including Plaintiff,  
25 of the dangerous risks associated with the subject product, including but not limited to the risk of  
26 tilting, perforation, fracture and migration which are associated with and did cause serious injury  
27 and/or death.  
28

1 51. Information provided by Cook to the medical community and to consumers concerning  
2 the safety and efficacy of its Cook Filters did not accurately reflect the serious and potentially fatal  
3 adverse events Plaintiff could suffer.

4 52. At all times relevant hereto, the Cook Filters were dangerous and presented a substantial  
5 danger to patients who were implanted with the Cook Filter, and these risks and dangers were known  
6 or knowable at the times of distribution and implantation in Plaintiff. Ordinary consumers would not  
7 have recognized the potential risks and dangers the Cook Filters posed to patients, because their use  
8 was specifically promoted to improve health of such patients.

9 53. Had adequate warnings and instructions been provided, Plaintiff would not have been  
10 implanted with the Cook filter and would not have been at risk of the harmful injuries described  
11 herein. The Cook Defendants failed to provide warnings of such risks and dangers to Plaintiff and  
12 their medical providers as described herein. Neither Plaintiff, nor Plaintiff's physicians knew, nor  
13 could they have learned through the exercise of reasonable care, the risks of serious injury and/or  
14 death associated with and/or caused by Cooks' Filters.

15 54. Cook Defendants knew or had knowledge that the warnings that were given failed to  
16 properly warn of the increased risks of serious injury and/or death associated with and/or caused by  
17 Cook Filters.

18 55. Plaintiff, individually and through her implanting physician, reasonably relied upon the  
19 skill, superior knowledge and judgment of the Cook Defendants.

20 56. Cook Defendants were under a continuing duty to warn Plaintiff and her physicians of  
21 the dangers associated with the filter.

22 57. Safer alternatives were available that were effective and without risks posed by Cook's  
23 Filters.

24 58. As a direct and proximate result of the Cook Filter's defects, as described herein,  
25 Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment.  
26 Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff  
27 has lost her ability to live a normal life and will continue to be so diminished into the future.  
28 Furthermore, Plaintiff has medical bills, both past and future, related to care because of the Cook

1 Filter's defects.

2 59. By reason of the foregoing, Cook Defendants are liable to Plaintiff for damages as a  
3 result of their failure to warn and/or adequately warn the Plaintiff and her healthcare professionals  
4 about the increased risk of serious injury and death caused by their defective Cook filters.

5 60. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks  
6 damages, including compensatory damages, exemplary damages, and punitive damages, together  
7 with interest, the costs of suit and attorneys' fees, and other such other and further relief as this Court  
8 deems just and proper.

9 **VI. Count II: Strict Products Liability – Failure to Warn**

10 61. Plaintiff repeats and realleges all previous paragraphs.

11 62. Cook Defendants have a duty to provide adequate warnings and instructions for their  
12 products including their Cook Filters, to use reasonable care to design a product that is not  
13 unreasonably dangerous to users.

14 63. At all times relevant to this action, Cook Defendants designed, tested, manufactured,  
15 packaged, labeled, marketed, distributed, promoted and sold their Cook Filters, placing the devices  
16 into the stream of commerce.

17 64. At all times relevant to this action, Cook's Filters were designed, tested, inspected,  
18 manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted,  
19 sold, packaged, supplied and/or distributed by Cook Defendants in a condition that was defective  
20 and unreasonably dangerous to consumers, including Plaintiff.

21 65. Cook Filters are defective in their design and/or formulation in that they are not  
22 reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the  
23 benefits associated with their design and formulation.

24 66. Cook Filters were expected to reach, and did reach, users and/or consumers including  
25 Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which  
26 they were manufactured and sold.

27 67. Physicians implanted as instructed via the Instructions for Use and in a foreseeable  
28 manner as normally intended, recommended, promoted, and marketed by the Cook Defendants.

1 Plaintiff received and utilized Cook Filters in a foreseeable manner as normally intended  
2 recommend, promoted, and marketed by the Cook Defendants.

3 68. Cook Filters were and are unreasonably dangerous in that, as designed, failed to perform  
4 safely when used by ordinary consumers, including Plaintiff, including when the filters were used as  
5 intended and in a reasonably foreseeable manner.

6 69. Cook Filters were and are unreasonably dangerous and defective in design or  
7 formulation for their intended use in that, when they left the hands of the manufacturers and/or  
8 supplier, they posed a risk of serious vascular and other serious injury which could have been  
9 reduced or avoided, inter alia, by the adoption of a feasible reasonable alternative design. There were  
10 safer alternative designs for the like products.

11 70. Cook Filters were insufficiently tested and caused harmful adverse events that  
12 outweighed any potential utility.

13 71. Cook Filters, as manufactured and supplied, were defective due to inadequate warnings,  
14 and/or inadequate clinical trials, testing, and study, and inadequate reporting regarding the results of  
15 the clinical trials, testing and study.

16 72. Cook Filters, as manufactured and supplied, were defective due to its no longer being  
17 substantially equivalent to its predicate device with regard to safety and effectiveness.

18 73. Cook Filters as manufactured and supplied by the Cook Defendants are and were  
19 defective due to inadequate post-marketing warnings or instructions because, after Cook Defendants  
20 knew or should have known of the risk of injuries from use and acquired additional knowledge and  
21 information confirming the defective and dangerous nature of its Cook Filters, Cook Defendants  
22 failed to provide adequate warnings to the medical community and the consumers, to whom Cook  
23 Defendants were directly marketing and advertising; and further, Cook Defendants continued to  
24 affirmatively promote their Cook Filters as safe and effective and as safe and effective as their  
25 predicate device.

26 74. As a direct and proximate result of the Cook Filter's defects, as described herein,  
27 Plaintiff suffered permanent and continuous injuries, pain and suffering, disability and impairment.  
28 Plaintiff has suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff

1 has lost her ability to live a normal life and will continue to be so diminished into the future.  
2 Furthermore, Plaintiff has medical bills, both past and future, related to care because of the Cook  
3 Filters' defects.

4 75. By reason of the foregoing, Cook Defendants are liable to Plaintiff for damages as a  
5 result of their failure to warn and/or adequately warn the Plaintiff and her healthcare professionals  
6 about the increased risk of serious injury and death caused by their defective Cook filters.

7 76. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks  
8 damages, including compensatory damages, exemplary damages, and punitive damages, together  
9 with interest, the costs of suit and attorneys' fees, and other such other and further relief as this Court  
10 deems just and proper.

11 **VII. Count III: Strict Products Liability – Failure to Warn**

12 77. Plaintiff repeats and realleges all previous paragraphs.

13 78. At all times relevant to this cause of action, the Cook Defendants were in the business of  
14 designing, developing, manufacturing, marketing and selling sophisticated medical devices,  
15 including its Cook Filters.

16 79. At all times relevant hereto, the Cook Defendants were under a duty to act reasonably to  
17 design, develop, manufacture, market and sell a product that did not present a risk of harm or injury  
18 to the Plaintiff and to those people receiving their Filters.

19 80. At the time of manufacture and sale of the Cook Filters, the Cook Defendants knew or  
20 reasonably should have known the Cook Filters:

- 21 a. were designed and manufactured in such a manner so as to present an unreasonable  
22 risk of fracture of portions of the device, as aforesaid;
- 23 b. were designed and manufactured so as to present an unreasonable risk of migration of  
24 the device and/or portions of the device, as aforesaid;
- 25 c. were designed and manufactured to have unreasonable and insufficient strength or  
26 structural integrity to withstand normal placement within the human body; and/or
- 27 d. were designed and manufactured so as to present an unreasonable risk of perforation  
28 and damage to the vena caval wall.

1 81. Despite the aforementioned duty on the part of the Cook Defendants, they committed  
2 one or more breaches of their duty of reasonable care and were negligent in:

- 3 a. unreasonably and carelessly failing to properly warn of the dangers and risks of harm  
4 associated with the Cook Filters, specifically its incidents fracture, migration,  
5 perforation and other failure;
- 6 b. unreasonably and carelessly manufacturing a product that was insufficient in strength  
7 or structural integrity to withstand the foreseeable use of normal placement within the  
8 human body;
- 9 c. unreasonably and carelessly designed a product that was insufficient in strength or  
10 structural integrity to withstand the foreseeable use of normal placement within the  
11 human body; and
- 12 d. unreasonably and carelessly designed a product that presented a risk of harm to the  
13 Plaintiff and others similarly situated in that it was prone to fail.

14 82. As a direct and proximate result of the Cook Filter's defects, as described herein,  
15 Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and  
16 impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the  
17 future. Plaintiff has lost her ability to live a normal life, and will continue to be so diminished into  
18 the future. Furthermore, Plaintiff has medical bills both past and future related to care because of the  
19 Cook Filter's defects.

20 83. By reason of the foregoing, Cook Defendants are liable to the Plaintiff for damages as a  
21 result of their failure to warn and/or adequately warn the Plaintiff and her healthcare professionals  
22 about the increased risk of serious injury and death caused by their defective Cook filters.

23 84. WHEREFORE, Plaintiff, demands judgment against the Cook Defendants and seeks  
24 damages, including: compensatory damages, exemplary damages, and punitive damages, together  
25 with interest, the costs of suit and attorneys' fees, and such other an further relief as this Court deems  
26 just and proper.

27 **VIII. Count IV: Negligence Per Se**

28 (Violation of 21 U.S.C. §§321, 331, 352 and 21 C.F.R. §§1.21, 801, 803, 807, 820)

1 85. Plaintiff repeats and realleges all previous paragraphs.

2 86. At all times herein mentioned, Defendants had an obligation not to violate the law,  
3 including the Federal Food, Drug and Cosmetic Act and the applicable regulations, in the  
4 manufacture, design, testing, production, processing, assembling, inspection, research, promotion,  
5 advertising, distribution, marketing, promotion, labeling, packaging, preparation for use, consulting,  
6 sale, warning and post-sale warning and other communications of the risks and dangers of Cook IVC  
7 Filters.

8 87. By reason of its conduct as alleged herein, Cook violated provisions of statutes and  
9 regulations, including but not limited to, the following:

- 10 a. Cook violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331 and 352,  
11 by misbranding its Cook IVC Filters;
- 12 b. Cook violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §321 in making  
13 statements and/or representations via word, design, device or any combination thereof  
14 failing to reveal material facts with respect to the consequences that may result from  
15 the use of Cook IVC Filters to which the labeling and advertising relates;
- 16 c. Cook violated 21 C.F.R. §1.21 in misleading the consumers and patients by  
17 concealing material facts in light of representations made regarding safety and  
18 efficacy of its Cook IVC Filters;
- 19 d. Cook violated 21 C.F.R. §801 in mislabeling its Cook IVC Filters as to safety and  
20 effectiveness of its products and by failing to update its label to reflect post-marketing  
21 evidence that Cook IVC Filters were associated with an increased risk of injuries due  
22 to tilting, fracture, migration and perforation;
- 23 e. Cook violated 21 C.F.R. §803 by not maintaining accurate medical device reports  
24 regarding adverse events of tilting, fracture, migration, perforation and complex  
25 removal procedures and/or misreporting these adverse events maintained via the  
26 medical device reporting system;
- 27 f. Cook violated 21 C.F.R. §807 by failing to notify the FDA and/or the consuming  
28 public when its Cook IVC Filters were no longer substantially equivalent with regard

1 to safety and efficacy with regard to post-marketing adverse events and safety signals;  
2 and

3 g. Cook violated 21 C.F.R. §820 by failing to maintain adequate quality systems  
4 regulation including, but not limited to, instituting effective corrective and  
5 preventative actions,

6 88. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks  
7 damages, including compensatory damages, exemplary damages, and punitive damages, together  
8 with interest, the costs of suit and attorneys' fees, and other such other and further relief as this Court  
9 deems just and proper.

10 **IX. Count V: Breach of Express Warranty**

11 89. Plaintiff repeats and realleges all previous paragraphs. Plaintiff, through her medical  
12 providers, purchased her Cook Filter from the Cook Defendants.

13 90. At all times relevant to this cause of action, the Cook Defendants were merchants of  
14 goods of the kind including medical devices and vena cava filters (i.e., Cook Filters).

15 91. At the time and place of sale, distribution and supply of the Cook Filter to Plaintiff (and  
16 to other consumers and the medical community), Cook expressly represented and warranted in their  
17 marketing materials, both written and orally, and in the IFUs, that the Cook Filters were safe, well-  
18 tolerated, efficacious, and fit for their intended purpose and were of marketable quality, that they did  
19 not produce any unwarned-of dangerous side effects, and that they were adequately tested.

20 92. At the time of Plaintiff's purchase from the Cook Defendants, the Cook Filters was not  
21 in a merchantable condition and the Cook Defendants breached their expressed warranties, in that  
22 the filter:

- 23 a. was designed in such a manner so as to be prone to a unreasonably high incident of  
24 fracture, perforation of vessels and organs, and/or migration;  
25 b. was designed in such a manner so as to result in an unreasonably high incident of  
26 injury to the organs of its purchaser; and  
27  
28

1 c. was manufactured in such a manner so that the exterior surface of the Cook Filter was  
2 inadequately, improperly and inappropriately designed causing the device to weaken  
3 and fail.

4 93. As a direct and proximate result of the Cook Filter's defects, as described herein,  
5 Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability, and  
6 impairment. Plaintiff suffered emotional trauma, harm, and injuries that will continue into the future.  
7 Plaintiff has lost her ability to live a normal life and will continue to be so diminished into the future.  
8 Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and have  
9 medical bills both past and future related to care because of the Cook Filter's defect.

10 94. By reason of the foregoing, the Cook Defendants are liable to Plaintiff for damages as a  
11 result of their breach express warranty

12 95. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks  
13 damages, including compensatory damages, exemplary damages, and punitive damages, together  
14 with interest, the costs of suit and attorneys' fees, and other such other and further relief as this Court  
15 deems just and proper.

16 **X. Count VI: Breach of Implied Warranty**

17 96. Plaintiff repeats and realleges all previous paragraphs.

18 97. At all relevant and material times, the Cook Defendants manufactured, distributed,  
19 advertised, promoted, and sold its Cook Filters.

20 98. At all relevant times, the Cook Defendants intended its Cook Filters be used in the  
21 manner that Plaintiff in fact used them.

22 99. Cook impliedly warranted their Cook Filters to be of merchantable quality, safe and fit  
23 for the use for which the Cook Defendants intended them and for which Plaintiff in fact used them.

24 100. The Cook Defendants breached their implied warranties as follows:

25 101. Cook failed to provide the warning or instruction and/or an adequate warning or  
26 instruction which a manufacturer exercising reasonable care would have provided concerning that  
27 risk, in light of the likelihood that its Cook Filters would cause harm;

28 102. Cook manufactured and/or sold their Cook Filters and said filters did not conform to

1 representations made by the Cook Defendants when they left their control;

2 103. Cook manufactured and/or sold their Cook Filters which were more dangerous than an  
3 ordinary consumer would expect when used in an intended or reasonably foreseeable manner, and  
4 the foreseeable risks associated with the Cook Filters' design or formulation exceeded the benefits  
5 associated with that design. These defects existed at the time the products left the Cook Defendants'  
6 control; and

7 104. Cook manufactured and/or sold their Cook Filters when they deviated in a material way  
8 from the design specifications, formulas or performance standards or from otherwise identical units  
9 manufactured to the same design specifications, formulas, or performance standards, and these  
10 defects existed at the time the products left the Cook Defendants' control.

11 105. The Cook Defendants' marketing of their Cook Filters was false and/or misleading.

12 106. Plaintiff, through her attending physicians, relied on these representations in determining  
13 which IVC filter to use for implantation in the Plaintiff.

14 107. Cooks' filters were unfit and unsafe for use by users as they posed an unreasonable and  
15 extreme risk of injury to persons using said products, such as the Plaintiff, and accordingly the Cook  
16 Defendants breached their expressed warranties and the implied warranties associated with the  
17 product.

18 108. The foregoing warranty breaches were a substantial factor in causing Plaintiff's injuries  
19 and damages as alleged.

20 109. As a direct and proximate result of the Cook Filters' defects, as described herein,  
21 Plaintiff has suffered permanent and continuous injuries, pain and suffering, disability and  
22 impairment. Plaintiff has suffered emotional trauma, harm and injuries that will continue into the  
23 future. Plaintiff lost her ability to live a normal life and will continue to be so diminished into the  
24 future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and  
25 has medical bills both past and future related to care because of the Cook Filters' defects.

26 110. By reason of the foregoing, Defendants are liable to Plaintiff for damages as a result of  
27 its breaches of implied warranty.

28 111. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks

1 damages, including compensatory damages, exemplary damages, and punitive damages, together  
2 with interest, the costs of suit and attorneys' fees, and other such other and further relief as this Court  
3 deems just and proper.

4 **XI. Count VII: Punitive Damages**

5 112. Plaintiff repeats and realleges all previous paragraphs.

6 113. At all times material hereto, the Cook Defendants knew or should have known their  
7 Cook Filters were inherently dangerous with respect to the risk of tilt, fracture, migration and/or  
8 perforation.

9 114. At all times material hereto, the Cook Defendants attempted to misrepresent and did  
10 knowingly misrepresent facts concerning the safety of their Cook Filters.

11 115. The Cook Defendants' misrepresentations included knowingly withholding material  
12 information from the medical community and the public, including Plaintiff's physicians, concerning  
13 the safety of their Cook Filters. The Cook Defendants' conduct was willful, wanton, and undertaken  
14 with a conscious indifference to the consequences that consumers of their product faced, including  
15 Plaintiff.

16 116. At all times material hereto, Cook knew and recklessly disregarded the fact that their  
17 Cook IVC Filters have an unreasonably high rate of tilt, fracture, migration and/or perforation.

18 117. Notwithstanding the foregoing, the Cook Defendants continued to market their Cook  
19 Filters aggressively to consumers, including the Plaintiff, without disclosing the aforesaid side  
20 effects.

21 118. The Cook Defendants knew of their Cook Filters' lack of warnings regarding the risk of  
22 fracture, migration, and/or perforation, but intentionally concealed and/or recklessly failed to  
23 disclose that risk and continued to market, distribute, and sell their Filters without said warnings so  
24 as to maximize sales and profits at the expense of the health and safety of the public, including  
25 Plaintiff, in conscious disregard of the foreseeable harm caused by Cook Filters.

26 **XII. Tolling of the Limitations Period**

27 119. The Cook Defendants' intentional and/or reckless failure to disclose information  
28 deprived the Plaintiff's physicians of necessary information to enable them to weigh the true risks of

1 using Cook Filters against their benefits.

2 120. As a direct and proximate result of the Cook Defendants' willful, wanton, careless,  
3 reckless, conscious, and deliberate disregard for the safety and rights of consumers including the  
4 Plaintiff, the Plaintiff has suffered and will continue to suffer severe and permanent physical and  
5 emotional injuries, as described with particularity, above. Plaintiff has endured and will continue to  
6 endure pain, suffering, and loss of enjoyment of life; and has suffered and will continue to suffer  
7 economic loss, including incurring significant expenses for medical care and treatment and lost  
8 wages.

9 121. The Cook Defendants' aforesaid conduct was committed with knowing, conscious,  
10 careless, reckless, willful, wanton, and deliberate disregard for the safety and rights of consumers  
11 including the Plaintiff, thereby entitling the Plaintiff to punitive damages in an amount appropriate to  
12 punish the Cook Defendants and deter them from similar conduct in the future.

13 122. WHEREFORE, Plaintiff demands judgment against the Cook Defendants and seeks  
14 damages, including compensatory damages, exemplary damages, and punitive damages, together  
15 with interest, the costs of suit and attorneys' fees, and other such other and further relief as this Court  
16 deems just and proper.

17 123. The Cook Defendants, through their affirmative misrepresentations and omissions,  
18 actively concealed from the Plaintiff and Plaintiff's healthcare providers the true and significant  
19 risks associated with Cook Filters.

20 124. As a result of the Cook Defendants' actions, Plaintiff and her prescribing physicians  
21 were unaware, and could not have reasonably known or have learned through reasonable diligence,  
22 that Plaintiff had been exposed to the risks identified in this Complaint, and that those risks were the  
23 result of Defendants' acts, omissions, and misrepresentations.

24 125. Accordingly, no limitations period ought to accrue until such time as Plaintiff knew or  
25 reasonably should have known of some causal connection between Plaintiff being implanted with a  
26 Cook Filter and the harm Plaintiff suffered as a result.

27 126. Additionally, the accrual and running of any applicable statute of limitations have been  
28 tolled by reason of the Cook Defendants' fraudulent concealment.

1 127. Additionally, the Cook Defendants are equitably estopped from asserting any limitations  
2 defense by virtue of their fraudulent concealment and other misconduct as described.

3 128. Additionally, the limitations period ought to be tolled under principles of equitable  
4 tolling.

5 **XIII. Prayer for Relief**

6 129. WHEREFORE, Plaintiff demands judgment against the Cook Defendants as follows:

- 7 a. Compensatory damages, including without limitation past and future medical  
8 expenses; past and future pain and suffering; past and future emotional distress; past  
9 and future loss of enjoyment of life; past and future lost wages and loss of earning  
10 capacity; and consequential damages;  
11 b. Punitive damages in an amount sufficient to punish Defendants and set an example;  
12 c. Disgorgement of profits;  
13 d. Restitution;  
14 e. Costs and fees of this action, including reasonable attorney's fees;  
15 f. Prejudgment interest and all other interest recoverable; and  
16 g. Such other additional and future relief as Plaintiff may be entitled to in law or in  
17 equity according to the claims pled herein.

18 **XIV. Demand for Jury Trial**

19 130. Plaintiff respectfully requests trial by jury in the above case as to all issues.  
20

21 Dated: 03/02/2020

Respectfully Submitted,

22 /s/ Matthew Skikos

23 Matthew Skikos

24 **Skikos, Crawford, Skikos & Joseph, LLP**

25 /s/ Basil E. Adham

26 Basil E. Adham, *to appear pro hac vice*

27 **Johnson Law Group**

28 *Attorneys for Plaintiff*